12/Req for Expedited Prosecution

1998-028-25DIV

IN RE APPLICATION OF :

MATTHEW T. SCHOLZ, :GROUP ART UNIT: 1615
ROBERT A. SCHERRER, :
NELDA M. MARECKI :
YEN-LANE CHEN AND :
JOAN K. BARKHAUS :

SERIAL NO: 08/855,933 :EXAMINER: P. KULKOSKY

FILED: May 14, 1997 :

FOR: BIOADHESIVE COMPOSITION AND PATCH

REQUEST FOR EXPEDITED PROSECUTION

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

The examiner is respectfully reminded that 37 CFR 1.607(b) provides in relevant part that:

> When an applicant seeks an interference with a patent, examination of the application... shall be conducted with special dispatch within the Patent and Trademark Office.

Respectfully submitted,

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13/ Second Request for Interference

1998-028-25 DIV

IN RE APPLICATION OF :

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FILED: MAY 14, 1997 :

FOR: BIOADHESIVE COMPOSITION AND PATCH

SECOND 37 CFR 1.607 REQUEST FOR AN INTERFERENCE WITH A PATENT

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

I. 37 CFR 1.607(a)(1)

The patent is U.S. patent No. 5,516,523 issued May 14, 1996 and naming Sonia J. Heiber, Charles D. Ebert, and Sirish C. Dave as inventors. The assignee at issue was TheraTech, Inc. of Salt Lake City, Utah.

II. 37 CFR 1.607(a)(2)

Applicants propose the following count, which is in the format approved by the Commissioner in Orikasa v. Oonishi, 10 USPQ2d 1999, 2003 (Comm'r 1990), and Davis v. Uke, 27 USPQ2d 1180, 1188 (Comm'r 1993):

Claim 1 in the Heiber et al. patent

OR

Claims 125, 132, 139, 145, or 150 in the Scholz et al. patent application.

An extra copy of the proposed count is submitted herewith for the examiner's use in filling out the form PTO-850. In addition, as explained in section IX of this request, a proposed form PTO-850 is submitted herewith for the examiner's convenience.

III. 37 CFR 1.607(a)(3)

All 24 claims in the Heiber et al. patent correspond to the proposed count. Indeed, the proposed count includes the only independent claims in that patent.

IV. 37 CFR 1.607(a)(4)

Previously submitted claims 125-144 and claims 145-150 presented in the 37 CFR 1.607(a)(4) amendment submitted herewith correspond to the proposed count. Indeed, the proposed count includes all of the independent claims in that group of claims.

While dependent claims 126-131, 133-138, 140-144, and 146-149 do not correspond exactly to the proposed count, applicants do not currently argue that any of those claims is drawn to a separate patentable invention within the meaning of 37 CFR 1.601(n).

V. 37 CFR 1.607(a)(5)

The terms of the application claims identified as corresponding to the proposed count can be applied to the disclosure of the application as follows:

Terms of the Claims	Application to the Disclosure of the Application
125. A method for mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to the oral cavity mucosa a system comprising	Page 4 lines 34-37 and page 5 lines 3-6.
an inner drug/	Page 3 lines 24-25.
enhancer/	Page 14 lines 14-31.

polymer	Page 3 lines 14-20
layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and	Page 3 line 25 - page 4 line 6 and page 4 lines 27-28.
an opposing surface in contact with and adhering to an overlying inert layer,	Page 4 lines 3-5
said inner layer containing an effective amount of a bile salt enhancer,	Page 14 lines 14-30.
from about 29 to 80% by weight of a hydrophilic polymer,	Page 3 lines 21-23. (100 parts of hydrophilic resin to 20-250 parts of hydrophobic resin.)
and an effective amount of a macromolecular drug.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21. Heparin (page 13 line 19); insulin (page 13 lines 5-6); and peptides and proteins (page 14 lines 19-21) are macromolecular drugs (i.e., have molecular weights greater than 500 daltons).
126. A method according to claim 125 wherein said bile salt enhancer is selected from the group consisting of sodium glycocholate, sodium taurocholate, and sodium tauro-24, 25-dihydrofusidate.	Page 14 lines 14-31.
127. A method according to claim 126 wherein said macromolecular drug is a member selected from the group consisting of polysaccharides, polypeptides, and proteins.	Page 14 lines 19-21; page 13 lines 3-6; insulin (page 13 line 5); and heparin (page 13 lines 10 and 19), a polysaccharide. Digoxin (Examples 2-4) is a polysaccharide having a molecular weight of 781.
128. A method according to claim 127, wherein said hydrophilic polymer is a member selected from the group consisting of acrylic acid polymers, maleic acid polymers, itaconic acid polymers, citraconic acid polymers, methacrylic acid polymers;	Page 5 line 10 - page 12 line 8. Applicants' preferred hydrophilic polymer, Carbopol® 934 is well recognized as being a hydrophilic polymer. See Kirk-Othmer, Encyclopedia of Chemical Technology, Vol. 20 pp. 216-219. (John Wiley & Sons, 1982)(Attachment A).

copolymers of a member selected from the group consisting of acrylic acid and methacrylic acid with a member selected from the group consisting of methyl vinyl ether and lower alkyl methacrylates;	Page 5 lines 10-23
and acrylic acid polymers cross-linked with a polyalkenyl ether selected from the group consisting of an allyl ether of sucrose and an allyl ether of pentaerythritol.	Page 5 line 24 - page 6 line 8.
129. A method according to claim 128 wherein the macromolecular drug is a polysaccharide.	Page 13 lines 19-21. Heparin is a macromolecular polysaccharide. See claims 8 and 9 of the '523 patent. Digoxin, as above noted, is a macromolecular polysaccharide.
130. A method according to claim 129 wherein the polysaccharide is heparin.	Page 13 lines 19-21.
131. A method according to claim 128 in the form of a film patch wherein said inert layer is a polymer which is nonadhesive to mucosal tissues and is substantially impermeable to the bile salt enhancer or the drug.	Page 18 lines 9-34.
132. A method for mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to an oral cavity mucosa a system comprising	Page 4 lines 34-37 and page 5 lines 3-6.
an inner drug/ enhancer/ polymer/	Page 3 lines 24-25. Page 14 lines 14-31. Page 3 lines 14-20.
layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and an	Page 3 line 25 - page 4 line 6 and page 4 lines 27-28.

opposing surface in contact with and adhering to an overlying inert layer

said inner layer containing from 0% to an effective amount by weight of a bile salt enhancer,

Page 14 lines 14-30.

about 29 to 80% by weight of a hydrophilic polymer, and

Page 3 lines 21-23 (100 parts hydrophilic polymer to 20-250 parts hydrophobic polymer).

an effective amount of a macromolecular drug.

Page 3 lines 24-25 and page 12 line 5 to page 13 line 21.

133. A method according to claim 132 wherein the bile salt enhancer is sodium taurocholate.

Page 14 lines 14-21.

134. A method according to claim 133 wherein said macromolecular drug is a member selected from the group consisting of polysaccharides, polypeptides, and

proteins.

Page 14 lines 19-21; page 13 lines 3-6; and insulin and heparin.

135. A method according to claim 134 wherein said hydrophilic polymer is a member selected from the group consisting of acrylic acid polymers,

methacrylic acid polymers,

copolymers of acrylic acid with a member selected from the group consisting of methyl vinyl ether and lower alkyl methacrylates,

methacrylic acid copolymers with a member selected from the group consisting of methyl vinyl ether and lower alkyl methacrylates,

Page 5 line 10 - page 12 line 8. Applicants' preferred hydrophilic polymer, Carbopol® 934 is well recognized as a hydrophilic polymer. See Attachment A.

Page 5 lines 17-22.

and polymers of acrylic acid cross-linked with a polyalkenyl polyether.	Page 5 lines 24-34
136. A method according to claim 135 wherein the macromolecular drug is a polysaccharide.	Page 13 lines 19-21.
137. A method according to claim 136 wherein the polysaccharide is heparin.	Page 13 lines 19-21.
138. A method according to claim 135 in the form of a film patch wherein said inert layer is a polymer which is nonadhesive to mucosal tissues and is substantially impermeable to the bile salt enhancer or drug.	Page 18 lines 9-34.
139. A method for mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to an oral cavity mucosa a system comprising	Page 4 lines 34-37 and page 5 lines 3-6.
an inner drug/	Page 3 lines 24-25.
polymer	Page 3 lines 14-20
layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer,	Page 3 line 25 - page 4 lines 6 and 27-28.
said inner layer containing from about 29 to about 80% of weight of a hydrophilic polymer	Page 3 lines 21-23.
and an effective amount of a macromolecular drug.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21. Heparin (page 13 line 19); insulin (page 13 lines 5-6); and peptides and proteins (page 14 lines 19-21) are macromolecular drugs.
140. A method according to claim 139 wherein the macromolecular drug is a member selected from the group consisting of polysaccharides, peptides, and proteins.	Page 14 lines 19-21; page 13 lines 3-6; page 13 line 5 (insulin); and page 13 lines 10 and 19 (heparin).

141. A method according to claim 140 wherein said hydrophilic polymer is a member selected from the group consisting of
polyacrylic acid,
polymethacrylic acid,
copolymers of acrylic acid with a member selected from the group consisting of methyl vinyl ether and lower alkyl methacrylates,
copolymers of methacrylic acid with a member selected from the group consisting of methyl vinyl ether and alkyl methacrylates,

Page 5 line 10 - page 12 line 8.

and polymers of acrylic acid cross-linked with a polyalkenyl polyether.

142. A method according to claim 141 wherein the macromolecular drug is a polysaccharide.

Page 13 lines 10 and 19 (heparin).

143. A method according to claim 142 wherein the polysaccaride is heparin.

Page 13 lines 10 and 19.

144. A method according to claim 139 wherein the macromolecular drug is heparin and

Page 13 lines 10 and 19.

the hydrophilic polymer is a linear polyacrylic acid resin cross-linked with a member selected from the group consisting of an allyl ether of sucrose and
an allyl ether of pentaerythritol.

Page 5 line 24 - page 6 line 8.

145. A method of achieving and/or maintaining a therapeutically effective blood level of a drug in a mammal, which method comprises the steps of:

Page 4 lines 13-33.

(a) adhering to an oral mucosal surface of a mammal a composition including an inert film backing and a bioadhesive on one surface of said inert film backing, wherein

Page 4 lines 4-6 and page 18 lines 9-34.

the bioadhesive includes (i) a particulate polymeric resin which is polymerized from monomers selected from the group consisting of acrylic acid, itaconic acid, citraconic acid, and methacrylic acid having at least about 55% by weight of carboxylic acid groups based on the weight of the resin and which comprises less than about 20% by weight, based on the total weight of all monomers in the polymer, of ethylenically unsaturated comonomers; and	Page 5 line 10 - page 6 line 7, particularly page 5 lines 11-23.
which particulate polymeric resin is dispersed substantially throughout from about 20 parts to about 250 parts by weight of a hydrophobic elastomeric synthetic polymer component, based on 100 parts by weight of the particulate polymeric resin,	Page 3 lines 14-31
said elastomeric synthetic polymer component being selected from the group consisting of a block styrene-butadiene-styrene copolymer, a block styrene-isoprene-styrene copolymer, a polyisobutylene, a polybutadiene, an isoprene rubber, a carboxy-functional polyisoprene, a hydroxy-functional polyisoprene, an acrylate elastomer, and a mixture of two or more of the foregoing;	Page 8 line 1- page 9 line 10.
(ii) a therapeutically effective amount of a drug selected from the group consisting of heparin, digoxin, polypeptides, proteins, and mixtures thereof; and	Page 12 line 37; page 13 lines 3-7, 11 and 19-21; page 14 lines 19-21 and Examples 2-4.
(iii) optionally, a penetration enhancing amount of a penetration enhancer;	Page 14 lines 14-31.
and (b) allowing the composition to remain adhered to said oral mucosal surface of a mammal for a time sufficient to release enough of said drug so that a therapeutically effective blood level of drug is achieved and/or maintained.	Page 4 lines 13-33, particularly lines 19-22.

146. A method according to claim 145 wherein the composition comprises an effective penetration enhancing amount of a penetration enhancer selected from the group consisting of sodium lauryl sulfate, cetyl pyridinium chloride, polysorbate 80, polyoxyethylene 9-lauryl ether, glyceryl monolaurate, oleic acid, sodium glycocholate, sodium taurocholate, and sodium tauro-24,25-dihydrofusidate.	Page 14 lines 14-30.
147. A method according to claim 146 wherein said drug is selected from the group consisting of digoxin, heparin, a polypeptide drug, and a protein drug.	Page 13 lines 3-6 and 19-21; page 14 lines 19-30; and Examples 2-4.
148. A method according to claim 147 wherein said penetration enhancer is selected from the group consisting of sodium glycocholate, sodium taurocholate, and sodium tauro-24,25-dihydrofusidate.	Page 14 lines 19-21 and 25-28.
149. A method according to claim 145 wherein said drug is digoxin.	Page 13 lines 19-21 and Examples 2-4.
150. A method according to claim 148 wherein said drug is digoxin.	Page 13 lines 15-21 and Examples 2-4.

VI. 37 CFR 1.607(a)(6)

37 CFR 1.607(a)(6) is irrelevant since the first request for interference and the accompanying 37 CFR 1.607(a)(4) amendment were submitted prior to one year from the date on which the Heibert et al. patent was granted.

VII. REQUEST FOR THE BENEFIT OF THE FILING DATE OF APPLICANTS' PRIORITY APPLICATIONS

Applicants claim priority under 35 USC 120 based upon application SN 08/510,046 filed on May 31, 1995, 07/842,222, filed on February 26, 1992, 07/607,863 filed on

November 01, 1990, 07/486,554 filed on February 27, 1990, and 07/431,664 filed on November 03, 1989. Applicants are entitled to the benefit of the filing dates of their earlier applications for interference purposes if the count reads on at least one adequately disclosed embodiment in the earlier application.[1] Assuming that the examiner recommends to the board applicants' proposed count, applicants clearly meet that standard. That this is so is demonstrated in the following table, which reads the terms of the count on their earlier applications.

Terms of the Count	Application of the Terms of the Count to the Disclosure of the 510,046 Application
A method of mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to an oral cavity mucosa a system comprising an inner drug/	Page 4 lines 34-37 and page 5 lines 3-6. Page 3 lines 24-25.
enhancer/	Page 14 lines 14-31.
polymer/	Page 3 lines 14-31.
layer having one surface in contact with and adhering to the mucosal tissue of the oral cavity and an opposing surface in contact with and adhering to an overlying inert layer	Page 3 line 25 - page 4 lines 6, 27, and 28.
said inner layer containing from about two to sixty percent by weight of a bile salt enhancer,	Page 14 lines 14-30.
five to sixty five percent by weight of a hydrophilic polymer and	Page 3 lines 21-23 (100 parts of hydrophilic polymer to 20-250 parts of hydrophobic polymer).

[1] Weil v. Fritz, 572 F.2d 856, 865-66 n. 16, 196 USPQ 600, 608 n. 16 (CCPA 1978).

an effective amount of a macromolecular drug having a molecular weight of at least 500 daltons.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21. Heparin (page 13 line 19); insulin (page 13 lines 5-6); and peptides and proteins (page 14 lines 19-21) are macromolecular drugs.
or	
A method for mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to the oral cavity mucosa a system comprising	Page 4 lines 34-37 and page 5 lines 3-6.
an inner drug/	Page 3 lines 24-25.
enhancer/	Page 14 lines 14-31.
polymer	Page 3 lines 14-20
layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and	Page 3 line 25 - page 4 line 6 and page 4 lines 27-28.
an opposing surface in contact with and adhering to an overlying inert layer,	Page 4 lines 3-5
said inner layer containing an effective amount of bile salt enhancer,	Page 14 lines 14-30.
from about 29 to 80% by weight of a hydrophilic polymer	Page 3 lines 21-23. (100 parts of hydrophilic resin to 20-250 parts of hydrophobic resin).
and an effective amount of a macromolecular drug.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21. Heparin (page 13 line 19); insulin (page 13 lines 5-6); and peptides and proteins (page 14 lines 19-21) are macromolecular drugs.
or	
A method for mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.

applying to an oral cavity mucosa a system comprising	Page 4 lines 34-37 and page 5 lines 3-6.
an inner drug/ enhancer/ polymer/	Page 3 lines 24-25. Page 14 lines 14-31. Page 3 lines 14-20.
layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer	Page 3 line 25 - page 4 line 6 and page 4 lines 27-28.
said inner layer containing from 0% to an effective amount by weight of a bile salt enhancer,	Page 14 lines 14-30
about 29 to 80% by weight of a hydrophilic polymer, and	Page 3 lines 21-23 (100 parts hydrophilic polymer to 20-250 parts hydrophobic polymer).
an effective amount of a macromolecular drug.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21.
or	
A method for mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to an oral cavity mucosa a system comprising	Page 4 lines 34-37 and page 5 lines 3-6.
an inner drug/	Page 3 lines 24-25.
polymer	Page 3 lines 14-20
layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer,	Page 3 line 25 - page 4 lines 6 and 27-28.
said inner layer containing from about 29 to about 80% of weight of a hydrophilic polymer	Page 3 lines 21-23.

and an effective amount of a macromolecular drug.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21. Heparin (page 13 line 19); insulin (page 13 lines 5-6); and peptides and proteins (page 14 lines 19-21) are macromolecular drugs.
or	
A method of achieving and/or maintaining a therapeutically effective blood level of a drug in a mammal, which method comprises the steps of:	Page 4 lines 13-33.
(a) adhering to an oral mucosal surface of a mammal a composition including an inert film backing and a bioadhesive on one surface of said inert film backing, wherein	Page 4 lines 4-6 and page 18 lines 9-34.
the bioadhesive includes (i) a particulate polymeric resin which is polymerized from monomers selected from the group consisting of acrylic acid, itaconic acid, citraconic acid, and methacrylic acid having at least about 55% by weight of carboxylic acid groups based on the weight of the resin and which comprises less than about 20% by weight, based on the total weight of all monomers in the polymer, of ethylenically unsaturated comonomers; and which particulate polymeric resin is dispersed substantially throughout from about 20 parts to about 250 parts by weight of a hydrophobic elastomeric synthetic polymer component, based on 100 parts by weight of the particulate polymeric resin,	Page 5 line 10 - page 6 line 7 particularly page 5 lines 11-23. Page 3 lines 14-31.
said elastomeric synthetic polymer component being selected from the group consisting of a block styrene-butadiene-styrene copolymer, a block styrene-isoprene-styrene copolymer, a polyisobutylene, a polybutadiene, an isoprene rubber, a carboxy-functional polyisoprene, a hydroxy-functional polyisoprene, an acrylate elastomer, and a mixture of two or more of the foregoing;	Page 8 line 1 - page 9 line 10.

(ii) a therapeutically effective amount of a drug selected from the group consisting of heparin, digoxin, polypeptides, proteins, and mixtures thereof; and	Page 12 line 37; page 13 lines 3-7, 11 and 19-21; page 14 lines 19-21 and Examples 2-4.
(iii) optionally, a penetration enhancing amount of a penetration enhancer;	Page 14 lines 14-31.
and (b) allowing the composition to remain adhered to said oral muscosal surface of a mammal for a time sufficient to release enough of said drug so that a therapeutically effective blood level of drug is achieved and/or maintained.	Page 4 lines 13-33, particularly lines 19-22.
or	
A method according to claim 148 wherein said drug is digoxin.	Page 13 lines 15-21 and Examples 2-4.

Since applicants' application is a straight continuation or division of application serial Nos. 08/510,046, 07/842,222, and 07/607,863, the disclosure of applicants' application is identical to the disclosures of those applications.

Application S.N. 431,664 discloses the hydrophilic polymer limitations of each of the alternative portions of the count at page 1 lines 2-28; the penetration enhancers at page 12 line 27 to page 13 line 7, particularly page 13 lines 2-5; and the macromolecular drug at page 10 line 20 to page 12 line 30 (including heparin, insulin, and human or animal growth hormones).

Example 13 at pages 26-27 of the 431,664 application describes patches containing 45% Carbopol® 910, a hydrophilic polymer, and 15% morphine sulfate, a macromolecular drug (molecular weight 669 daltons).

Application S.N. 486,554 carries forward the above disclosures from the 431,664 application at page 3 lines 8-34, page 5 line 4 to page 6 line 14, page 11 line 1 to page 12 line 33, page 13 lines 6-23, and Example 13 at pages 25-26.

VIII. 37 CFR 1.608

37 CFR 1.608 is irrelevant since the effective filing date of this application precedes the effective filing date of the Heider et al. patent.

IX. SUBMISSION OF PROPOSED FORM PTO-850

Submitted herewith for the convenience of the examiner is a proposed form PTO-850.

Respectfully submitted,

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Item 6:

THE COUNT

Claim 1 in the Heiber et al. patent

OR

Claims 125, 132, 139, 145, or 150 in the Scholz et al. patent application.

Claim 1 of the Hieber et al. patent consists of the following:

A method of mucosally administering a macromolecular drug to the oral cavity comprising applying to an oral cavity mucosa a system comprising an inner drug/enhancer/polymer/ layer having one surface in contact with and adhering to the mucosal tissue of the oral cavity and an opposing surface in contact with and adhering to an overlying inert layer said inner layer containing from about two to sixty percent by weight of a bile salt enhancer, five to sixty five percent by weight of a hydrophilic polymer and an effective amount of a macromolecular drug having a molecular weight of at least 500 daltons.

Claims 125, 132, 139, 145, or 150 in the Scholz et al. patent application consist of the following:

125. A method for mucosally administering a macromolecular drug to the oral cavity comprising applying to the oral cavity mucosa a system comprising an inner drug/enhancer/polymer layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer, said inner layer containing an effective amount of a bile salt enhancer, from about 29 to 80% by weight of a hydrophilic polymer, and an effective amount of a macromolecular drug.

132. A method for mucosally administering a macromolecular drug to the oral cavity comprising applying to an oral cavity mucosa a system comprising an inner drug/enhancer/polymer/layer having one surface adapted to contact the mucosal tissue of the

oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer said inner layer containing from 0% to an effective amount by weight of a bile salt enhancer, about 29 to 80% by weight of a hydrophilic polymer, and an effective amount of a macromolecular drug.

139. A method for mucosally administering a macromolecular drug to the oral cavity comprising applying to an oral cavity mucosa a system comprising an inner drug/polymer layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer, said inner layer containing from about 29 to about 80% of weight of a hydrophilic polymer and an effective amount of a macromolecular drug.

145. A method of achieving and/or maintaining a therapeutically effective blood level of a drug in a mammal, which method comprises the steps of:

(a) adhering to an oral mucosal surface of a mammal a composition including an inert film backing and a bioadhesive on one surface of said inert film backing, wherein the bioadhesive includes (i) a particulate polymeric resin which is polymerized from monomers selected from the group consisting of acrylic acid, itaconic acid, citraconic acid, and methacrylic acid having at least about 55% by weight of carboxylic acid groups based on the weight of the resin and which comprises less than about 20% by weight, based on the total weight of all monomers in the polymer, of ethylenically unsaturated comonomers; and which particulate polymeric resin is dispersed substantially throughout from about 20 parts to about 250 parts by weight of a hydrophobic elastomeric synthetic polymer component, based on 100 parts by weight of the particulate polymeric resin, said elastomeric synthetic polymer

component being selected from the group consisting of a block styrene-butadiene-styrene copolymer, a block styrene-isoprene-styrene copolymer, a polyisobutylene, a polybutadiene, an isoprene rubber, a carboxy-functional polyisoprene, a hydroxy-functional polyisoprene, an acrylate elastomer, and a mixture of two or more of the foregoing; (ii) a therapeutically effective amount of a drug selected from the group consisting of heparin, digoxin, polypeptides, proteins, and mixtures thereof; and (iii) optionally, a penetration enhancing amount of a penetration enhancer; and

(b) allowing the composition to remain adhered to said oral mucosal surface of a mammal for a time sufficient to release enough of said drug so that a therapeutically effective blood level of drug is achieved and/or maintained.

150. A method according to claim 148 wherein said drug is digoxin.

Scholz et al. claims 146-148, from which claim 150 also depend, read as follows:

146. A method according to claim 145 wherein the composition further comprises an effective penetration enhancing amount of a penetration enhancer selected from the group consisting of sodium lauryl sulfate, cetyl pyridinium chloride, polysorbate 80, polyoxyethylene 9-lauryl ether, glyceryl monolaurate, oleic acid, sodium glycocholate, sodium taurocholate, and sodium tauro-24,25-dihydrofusidate.

147. A method according to claim 146 wherein said drug is selected from the group consisting of digoxin, heparin, a polypeptide drug, and a protein drug.

148. A method according to claim 147 wherein said penetration enhancer is selected from the group consisting of sodium glycocholate, sodium taurocholate, and sodium tauro-24,25-dihydrofusidate.

No claim of the Heiber et al. patent or the Scholz et al. application is exactly the same as the count, but each alternative element of the count is exactly the same as one of Heiber et al.'s claim 1 or Sholz et al.'s claims 125, 132, 139, 145, or 150.

Item 7:

Claim 1 of the Heiber et al. patent and claims 125, 132, 139, 145, and 150 of the Scholz et al. application each constitute an alternative portion of the count and, thus, define the same patentable invention as the count.

While Scholz et al.'s claims 126-131, 133-138, 140-144, and 146-149 do not form an alternative within the count, Scholz et al. have not contended that any of those claims defines an invention which is separately patentable from the invention defined by the count.

All of the Heiber et al. claims 1-24 parallel claims to the corresponding systems (compositions) which were prosecuted in parent application 08/027,508. During the prosecution of that application, the examiner rejected claims 1-24 as a unit over two prior art references in combination, Paper No. 2 mailed May 21, 1993. In his action, the examiner expressly held that the limitations in the dependent claims were modifications within the expected skill of the prior art.

The Heiber et al. response in parent application 08/027,508 (Paper No. 3 filed October 25, 1993) likewise treated all of the claims 1-24 as standing or falling together. Thus, there is no basis on the record to regard any of claims 1-24 as defining a separately patentable invention.

Item 8:

No claims are initially designated as not corresponding to the count.

Item 9:

There is only one count.

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